

## DETAILED ACTION

### *Election/Restrictions*

1. This application contains the following inventions or groups of inventions, which are not so linked as to form a single inventive concept under PCT Rule 13.1. Restriction is required under 35 U.S.C. 121 and 372.

Group I. Claims 33-59, drawn to a method for improving tolerance in a graft-recipient.

Group II. Claims 60-70, drawn to a method for mobilizing hematopoietic stem cells in a donor.

2. The invention listed as groups II and I do not relate to a single inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups II and I are different processes. The processes have different inventive steps, targeting different subjects and for achieving different goals. 37 CFR 1.475 (b) states "AN INTERNATIONAL OR A NATIONAL STAGE APPLICATION CONTAINING CLAIMS TO DIFFERENT CATEGORIES OF INVENTION WILL BE CONSIDERED TO HAVE UNITY OF INVENTION IF THE CLAIMS ARE DRAWN **ONLY TO ONE** OF THE FOLLOWING COMBINATIONS OF CATEGORIES: (1) A PRODUCT AND A PROCESS SPECIALLY ADAPTED FOR THE MANUFACTURE OF SAID PRODUCT; OR (2) A PRODUCT AND A PROCESS OF USE OF SAID PRODUCT; OR (3) A PRODUCT, A PROCESS SPECIALLY ADAPTED FOR THE MANUFACTURE OF THE SAID PRODUCT, AND A USE OF THE SAID PRODUCT; OR (4) A PROCESS AND AN APPARATUS OR MEANS SPECIFICALLY DESIGNED FOR CARRYING OUT THE SAID PROCESS; OR (5) A PRODUCT, A PROCESS SPECIALLY ADAPTED FOR THE MANUFACTURE OF THE SAID PRODUCT, AND AN APPARATUS OR MEANS

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SPECIFICALLY DESIGNED FOR CARRYING OUT THE SAID PROCESS.” Since multiple processes of using/producing are claimed, unity of invention is lacking and restriction is required. The differences in the special technical features of the Inventions I and II are further underscored by their divergent classification and independent search criteria.

Accordingly, Groups II and I are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. Upon election of an invention for examination in this application, further election of a species is necessary. The species is defined as a combination of the following factors:

Upon election of group I, further elect:

a. A specific means for disrupting sex steroid-mediated signaling in the patient, in the case of chemical castration, a specific drug or a specific combination of drugs, e.g. leuprolide, abarelix, formestane or bicalutamide;

b. A specific subject for intervention, i.e. whether the patient has an atrophied thymus and has a disease;

c. A specific stem cells to be administered to the patient, e.g. CD34+ HSCs, myeloid progenitor cells or a specific type of epithelial stem cells, and consequently a specific type of chimera, and the presence or absence of genetic modification of the cells;

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d. A specific cytokine or growth factor or a specific combination thereof, such as IL-2 or KGF.

Upon election of group II, further elect:

a. A specific means for disrupting sex steroid-mediated signaling in the patient, in the case of chemical castration, a specific drug or a specific combination of drugs, e.g. leuprolide, abarelix, formestane or bicalutamide;

b. A specific cytokine or growth factor or a specific combination thereof, such as IL-2 or KGF.

The different species are directed to divergent subject matter and require different search criteria. It would impose serious search burden if examined together.

4. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention and a list of claims readable on the elected invention and species, to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

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5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on 571-272-0739. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

*/Q. JANICE LI/  
Primary Examiner, Art Unit 1633*